John Dalli
Member of the European Commission

Brussels,
CAB D (2012) Ares

Dear Mr Bos,
[redacted]

Thank you for your letter of 6 February in which you outlined your views regarding enhanced control on notified bodies and listed a number of improvements of the legislative system in order to learn lessons from the PIP case.

This case has pinpointed a number of weaknesses in the regulatory framework which we had already intended to address in the forthcoming revision of the legislation, scheduled for later this year. Indeed, within the context of the ongoing impact assessment and preparatory work for the revised legislation we have included provisions on, among others, the strengthened supervision of notified bodies.

Whilst the designation and monitoring of notified bodies should remain the ultimate responsibility of the individual Member State, I consider that elements of a shared responsibility should be built into the process by means of joints assessments of the bodies with the participation of assessors of other Member States and of the Commission.

I also consider that a mechanism needs to be set up to allow early information about high risk and novel devices coming to the market and the scrutiny, on an ad hoc basis, of individual conformity assessments regarding such products before a certificate is issued. I agree with you that such mechanism must be predictable, proportionate, transparent and expeditious.

My services are working on the details of the legislative proposals and will take your views into account.

Some of your suggestions for improving the legislative system can, in my view, already be implemented now under the current directives. For example, they make provisions that notified bodies can make unannounced visits. We need to come to a common understating about the frequency of such unannounced visits.

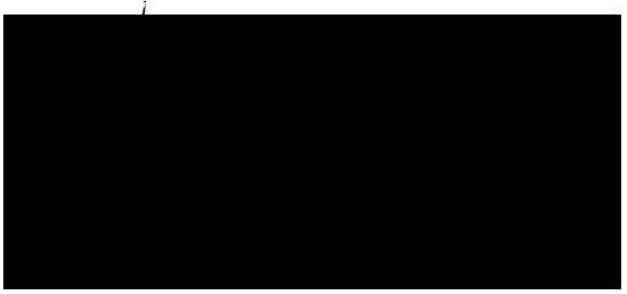
This is part of a list of measures for immediate action under the existing medical device legislation that I sent to the Health Ministers of all EU Member States, EFTA countries and Turkey, asking them for their full support to implement those measures. The objective is that Member States and Commission act now and within the existing legal framework to tighten up controls, provide a better guarantee of the safety of medical technology, especially implantable and other high risk devices, and begin to restore patient confidence. The details of the proposed action can be found in the attached table.

Dr. Gert Bos, President Team-NB
[redacted]
Boulevard Frère Orban 35A
4000 Liège

European Commission, B-1049 Brussels - TELEPHONE: +32 2 298 65 13 - FAX: +32 2 298 84 94 - E-MAIL: john.dalli@ec.europa.eu

I am interested in discussing with senior managers of some notified bodies about their contribution to strengthening the current regulatory system and how they see the notified bodies' role in the future legislation. Ideally, this meeting should take place in March and I would suggest that our respective secretariats agree on a suitable date.

Yours sincerely,



Encl. List of measures for immediate action under existing legislation